



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

Ms. Marie Maks  
Nichino America, Inc.  
4550 New Linden Hill Road, Suite 501  
Wilmington, DE 19808

Dear Ms. Maks:

MAY 29 2008

Subject: Flutolanil Technical (EPA Reg. No. 71711-5)  
Your label amendment dated 18 April 2006.  
OPP Decision Number 367043

The label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended is acceptable provided you make the following changes:

Page 2 - Move the sentence "It is a violation of Federal law to use this product in a manner which is inconsistent with its labeling." to page 1 immediately after the heading "Directions for Use."

Page 2 - Storage and Disposal:

Add "Do not contaminate water, food or feed by storage or disposal." immediately after the heading "Storage and Disposal."

You must submit the following as conditions of registration:

1. Analytical reference standards of flutolanil and its metabolites as requested by the National Pesticide Standard Repository (Standards.Pesticide@epa.gov). For the expired reference standards, you must either recertify the lot in the repository and send in an updated certificate of analysis (COA), or submit new standards (different lot #) if the previous lots will not be recertified. If new COAs are being submitted, they should be faxed to the Repository at 410-305-2999.  
This item is due September 1, 2008.
2. The following additional data are required to support the enforcement method AU/95R/04:
  - (a) additional radiovalidation data from all previously submitted metabolism studies;  
This item is due June 1, 2009.
  - (b) additional fortification recovery data for flutolanil and its metabolites on potato.  
This item is due June 1, 2009.

(c) A confirmatory method is required for AU/95R/04 that is able to confirm the identity and amount of all residues of concern. This method must be rewritten to include instructions for analysis of additional crops including potatoes and rotational crops for which tolerances have been established.

This item is due June 1, 2009.

Please submit one copy of your final printed labeling before you release the product for shipment. A stamped copy of the label is enclosed for your records. If you have any questions, please contact Lisa Jones on my team at (703) 308-9424 or at [jones.lisa@epa.gov](mailto:jones.lisa@epa.gov).

Sincerely,



Mary L. Waller  
Product Manager (21)  
Fungicide Branch  
Registration Division (7505P)

Enclosure: Stamped Label  
November 27, 2007 Flutolanil. Human Health Risk Assessment. Requests for Inadvertent or Indirect Tolerances for Use on Soybean, Wheat, Corn and Cotton  
November 1, 2007 Flutolanil Chronic Aggregate Dietary (Food and Drinking Water) Exposure and Risk Assessment for the Section 3 Registration Action  
November 26, 2007 Flutolanil. Petitions for Establishment of Tolerances for Indirect or Inadvertent Residues in/on Corn, Cotton, Soybean, and Wheat Commodities. Summary of Analytical Chemistry and Residue Data. PRIA R17. PP#0F6159 (Soybean and Wheat) and PP#6F7070 (Corn and Cotton).

## Flutolanil Technical

For Formulating Use Only

**ACTIVE INGREDIENTS:**

N-[3-(1-methylethoxy)phenyl]-2-(trifluoromethyl)benzamide.....98.3%

**OTHER INGREDIENTS**.....1.7%

**TOTAL**.....100.0%

EPA Reg. No. 71711-5

EPA Est. No. 67017-JP-2

### KEEP OUT OF THE REACH OF CHILDREN CAUTION

FIRST AID	
If on skin or clothing	Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

### PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS CAUTION

Harmful if absorbed through skin. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

**Environmental Hazards**

Do not discharge effluent containing this product directly into lakes, streams, ponds, estuaries, oceans or public waters unless this product is specifically identified and addressed in a NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency.

### DIRECTIONS FOR USE

Only for formulation into a fungicide, for:

- (1) The following uses: peanuts, rice, potatoes, turf, ornamentals;
- (2) Uses for which USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration;
- (3) Uses for experimental purposes that are in compliance with USEPA requirements.

**ACCEPTED  
with COMMENTS  
In EPA Letter Dated:  
MAY 29 2008**

**Under the Federal Insecticide,  
Fungicide, and Rodenticide Act,  
as amended, for the pesticide  
registered under EPA Reg. No.**

Active Ingredient Made in Japan for  
**Nichino America Inc.**  
4550 New Linden Hill Rd., Suite 501  
Wilmington, DE 19808  
www.nichino.net

71711-5

**Formulation Information**

Each formulator is responsible for obtaining EPA registration for his/her own end-use products. Technical information on formulations of this product as well as its physical and chemical characteristics may be obtained from Nichino America, Inc. It is a violation of Federal Law to use this product in a manner which is inconsistent with its labeling.

**STORAGE AND DISPOSAL**

**STORAGE:** Store in original container and keep closed. Store in a cool, dry place.

**PESTICIDE DISPOSAL:** Do not contaminate water, food or feed by storage or disposal. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

**CONTAINER DISPOSAL:** Completely empty bag by shaking and tapping sides to loosen clinging particles. Empty residue into formulation equipment. Then dispose of liner in a sanitary landfill or by incineration, or if allowed by state and local authorities by burning. If burned stay out of smoke. If drum is contaminated and cannot be reused, dispose of in the same manner.

**IMPORTANT: READ BEFORE USE**

By using this product, user or buyer accepts the following conditions, warranty, disclaimer of warranties and limitations of liability.

**CONDITIONS:** The directions for use of this product are believed to be accurate and must be followed carefully. However, because of extreme weather and soil conditions, use methods and other factors beyond the control of Nichino America, Inc. (NAI), it is impossible for NAI to eliminate all risks associated with the use of this product. As a result, crop injury or ineffectiveness is always possible. To the extent allowable under applicable law, all such risks are assumed by the user or buyer.

**DISCLAIMER OF WARRANTIES:** TO THE EXTENT ALLOWABLE UNDER APPLICABLE LAW, THERE ARE NO WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, WHICH EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of NAI is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. To the extent allowable under applicable law, NAI disclaims any liability whatsoever for incidental or consequential damages, including, but not limited to, liability arising out of breach of contract, express or implied warranty (including warranties of merchantability and fitness for a particular purpose), tort, negligence, strict liability or otherwise.

**LIMITATIONS OF LIABILITY:** TO THE EXTENT ALLOWABLE UNDER APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT THE ELECTION OF NICHINO AMERICA, THE REPLACEMENT OF PRODUCT.